Notice of Allowability	Application No.	Applicant(s)	
	10/014,519	WU ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the interview held on 9/20/2006*.

2. ☒ The allowed claim(s) is/are *1 – 4, 9, 13, 14, 16 18, 19, 21 – 23, 25, 26, 33, 35 – 37, 39 and 41 – 51*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Drawings

The drawings were received on 6/26/2006. These drawings are acceptable.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with R. Bone on 9/20/2006.

The application has been amended as follows:

1. Claim 1. A microfluidic device comprising:

a lysing module configured to receive a cell-containing microdroplet;

an actuator located upstream of the lysing module and configured to create a difference between an upstream pressure and a downstream pressure acting on the cell-containing microdroplet to move the microdroplet towards the lysing module;

a vented positioning element located upstream of the lysing module and downstream of the actuator, wherein the vented positioning element is configured to stop the cell-containing microdroplet in a lysing position with respect to the lysing module, and wherein the vented positioning element is configured to position a portion of

the cell-containing microdroplet downstream of the vented positioning element in the lysing position; and

a lysing mechanism within the lysing module, configured to release intracellular material from cells within the cell-containing microdroplet in the lysing position with respect to the lysing module.

2. Claims 12, 27 – 30, 32 and 40 have been canceled.

Allowable Subject Matter

Claims 1 – 4, 9, 13, 14, 16 18, 19, 21 – 23, 25, 26, 33, 35 – 37, 39 and 41 – 51 are allowed.

The following is an examiner's statement of reasons for allowance:

1. Regarding claim 1, the cited prior art neither teach nor fairly suggest a microfluidic device comprising:

a lysing module configured to receive a cell-containing microdroplet;

an actuator located upstream of the lysing module and configured to create a difference between an upstream pressure and a downstream pressure acting on the cell-containing microdroplet to move the microdroplet towards the lysing module;

a vented positioning element located upstream of the lysing module and downstream of the actuator, wherein the vented positioning element is configured to stop the cell-containing microdroplet in a lysing position with respect to the lysing module, and wherein the

vented positioning element is configured to position a portion of the cell-containing microdroplet downstream of the vented positioning element in the lysing position; and

a lysing mechanism within the lysing module, configured to release intracellular material from cells within the cell-containing microdroplet in the lysing position with respect to the lysing module.

2. Regarding claim 16, the cited prior art neither teach nor fairly suggest a microfluidic device comprising:

a lysing module configured to receive a microdroplet of cell-containing sample;

a lysing mechanism within the lysing module configured to release intracellular contents from cells in the microdroplet of cell-containing sample within the lysing module;

a first gas actuator situated upstream of the lysing module and configured to move the microdroplet of cell-containing sample downstream to overlap the lysing module;

a positioning element located downstream of the lysing module and configured to inhibit downstream movement of the cell-containing sample, thereby positioning at least some of the cell-containing sample in a lysing position with respect to the lysing module; and

a second gas actuator disposed upstream from the lysing module but downstream from the first gas actuator to provide a gas pressure sufficient to:

(a) prepare a lysed microdroplet comprising intracellular contents released from cells of the cell-containing sample within the lysing

module, the microdroplet having a length equal to a distance between the second gas actuator and the positioning element; and

(b) move the lysed microdroplet downstream of the lysing module and past the positioning element.

3. Regarding claim 33, the cited prior art neither teach nor fairly suggest a method for lysing a microdroplet of cell-containing liquid comprising the steps of:

introducing the microdroplet of cell-containing liquid to a lysing module of a microfluidic device;

inhibiting the microdroplet of a cell-containing liquid from moving downstream from the lysing module;

actuating a lysing mechanism to release intracellular contents from cells of the cell-containing liquid within the lysing module; and

providing a gas pressure sufficient to separate a first portion of the microdroplet of cell-containing liquid located within the lysing module from a second portion of the microdroplet of cell-containing liquid located upstream of the lysing module, thereby preparing a lysed microdroplet comprising intracellular contents released from cells of the cell-containing liquid within the lysing module.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.